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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,043	04/12/2004	Barrie Tan	BT-001	4102

7590 06/24/2005  
Kirk Hahn, Ph.D  
14431 Holt Ave.  
Santa Ana, CA 92705

EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/823,043

**Applicant(s)**

TAN ET AL.

**Examiner**

Susan B. McCormick-Ewoldt

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on April 4, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a composition comprising annatto extract, classified in class 424, subclass 725, for example.
- II. Claim 18, drawn to a method to administer annatto extract to produce beneficial effects, classified in class 424, subclass 725, for example.
- III. Claim 19, drawn to a method to reduce skin maladies, classified in class 424, subclass 725, for example.
- IV. Claims 20-21, drawn to a method to reverse insulin resistance, classified in class 424, subclass 725, for example.
- V. Claim 22, drawn to a method to reduce cancer, classified in class 424, subclass 725, for example.
- VI. Claim 23, drawn to a method to reduce cardio vascular diseases and diabetes, classified in class 424, subclass 725, for example.
- VII. Claim 24, drawn to a method to treat prediabetes and diabetes, classified in class 424, subclass 725, for example.

Invention I and inventions II, III, IV, V, VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, there are numerous other products that can be used to reduce skin maladies or reverse insulin resistance or reduce cancer or reduce cardiovascular disease or to treat prediabetes and diabetes.

Inventions II, III, IV, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the different inventions are all unrelated because different methods of treatment.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II or III or IV or V or VI or VII, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention.

Claim 4 is generic to a plurality of disclosed patentably distinct species comprising active ingredients as claimed in claim 4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, (i.e. elect one from a) soy or corn or rice bran or palm or olive or wheat germ or oat bran or sunflower seed or cottonseed or cranberry seed or litchi seed or combinations thereof) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 4 is generic.

Claim 18 is generic to a plurality of disclosed patentably distinct species comprising a group producing a beneficial effect as claimed in claim 18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, (i.e. elect one from lowering CRP or protects against inflammation or lowers cholesterol or decreases materials or improves arterial vasculature or reduces osteoporosis or increases bone mineralization or enhances immune system or lowers lipids or reverses insulin resistance or increases natriuresis or extending life or combinations thereof) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 18 is generic.

Claim 21 is generic to a plurality of disclosed patentably distinct species comprising lowering the risk of a disease as claimed in claim 21. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, (i.e. elect one from CVD or T2DM or hypertension or PCOS or fatty liver disease or combinations thereof) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

Claim 23 is generic to a plurality of disclosed patentably distinct species comprising active ingredients as claimed in claim 23. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, (i.e. elect one from phytosterols or oryzanols or policosanols or pentathine or red yeast rice or oat bran or garlic or gugul lipids or chitosan or soy protein or CoQ10 or carnitine or magnesium or calcium or D-tyroxine or fibers or omega-3s or lecithin or combinations thereof) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

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Claim 24 is generic to a plurality of disclosed patentably distinct species comprising active ingredients as claimed in claim 24. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, (i.e. elect one from banaba extract or lipoic acids or chromium (all compounded forms) or B vitamins (including niacin) or combinations thereof) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 24 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

*Susan D. Coe*  
6-22-05  
**SUSAN COE**  
**PRIMARY EXAMINER**